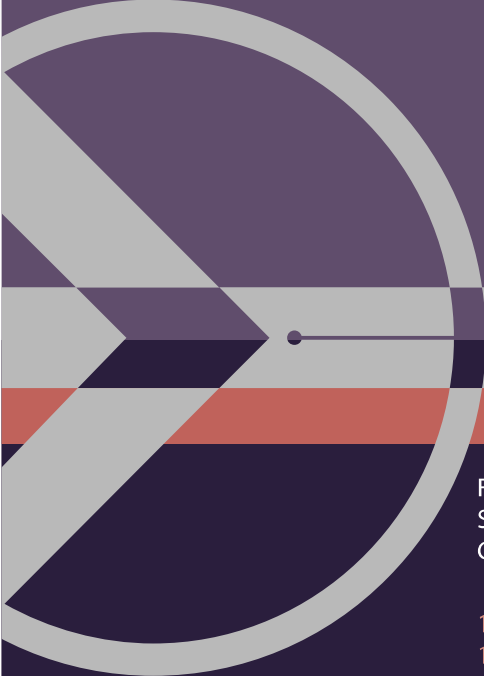


# Pharmaceutical Medicine Modules

Spring 2014

Barbara Baroutsou MD, PhD, EMAUD Internist ,chair SFEE Medical  
Directors' Committee



OPEN DAY PRESENTATION  
Tuesday, March 4, 2014 – 3:00 p.m.

## PROFESSIONAL STUDIES

### PHARMACEUTICAL MEDICINE MODULES

For Medical Directors, Medical Advisors, CPMs, Senior CRAs, Researchers, Scientists, Healthcare Professionals, MDs, Pharmacists, Health Economists, Medical Managers, CRAs, Medical Science Liaisons, Regulatory Officers, Pharmacovigilance Experts

15:00-16:00      Pharmaceutical Medicine Modules: 2014 Seminars and last year's feedback.  
16:00-17:00      Depiction of clinical research in GREECE. A recent study of the National School of Public Health (ESDY). Announcement of results.

Upper Level – John S. Bailey Library, DERE – The American College of Greece  
6 Gravias Street, Aghia Paraskevi

**ΣfEE**

Information:  
DEREE Graduate School of Arts & Sciences  
tel.: +30 210 600 9800 ext. 1332 , e-mail: professional@acg.edu  
<http://www.acg.edu/graduate/graduate-academics/professional-studies/sfee>  
S f

Graduate School of Arts & Sciences  
 **DEREE**

# Spring 2014

- Continuous Professional Education in Pharmaceutical Medicine not existing on Greek University –Medical School and Health Science schools
- SFEE initiative on CPE was welcomed by ACG Graduate School of Arts & Science
  - Academics, regulators, practitioners, MDs, pharma staff
- The third consecutive year of SFEE –ACG DERE E Continuous Professional education :Modules on Pharmaceutical Medicine
  - 2012 – 80 students in 3 courses
  - 2013 – 130 students in 7 courses
  -
- SFEE-DERE E CPE organized along 4 main pillars
  - Scientific, Clinical, Operational and Health Policy

# Spring 2013

- 7 Courses

10 weeks

1. Medical Affairs in Pharmaceutical Medicine
2. Pharmacoepidemiology
3. Introduction to Clinical Research

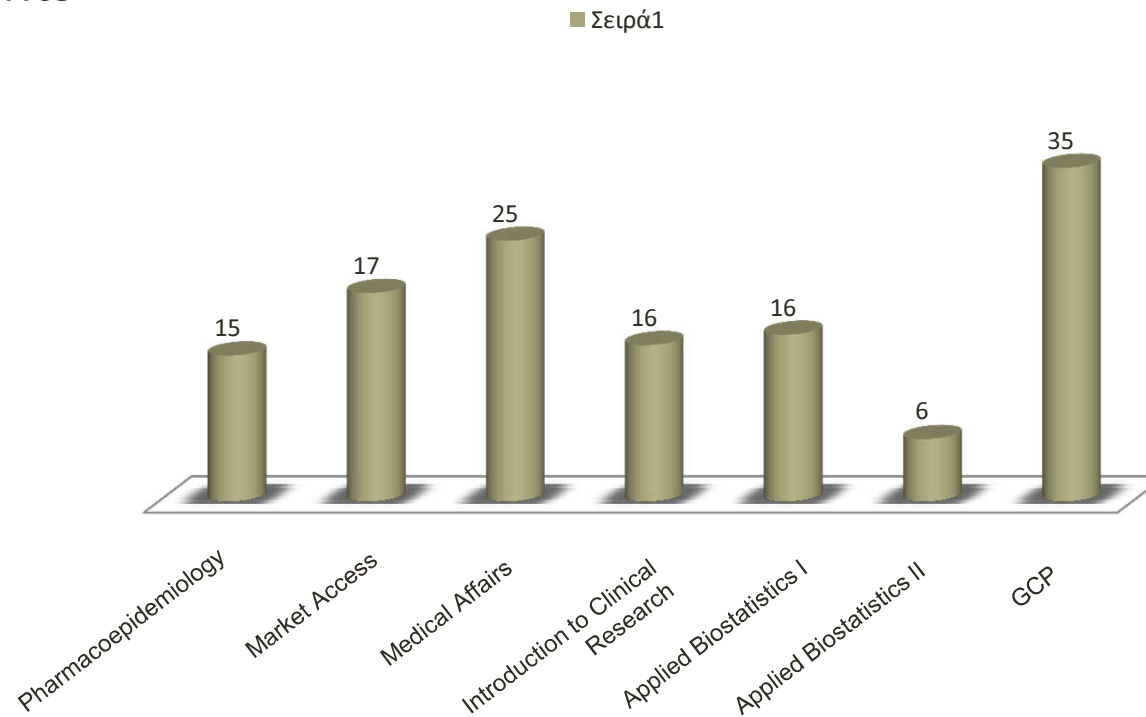
2 days

4. Applied Biostatistics I
5. Applied Biostatistics II
6. GCP for Investigators
7. Market Access Forum

# Spring 2013

- 130 students

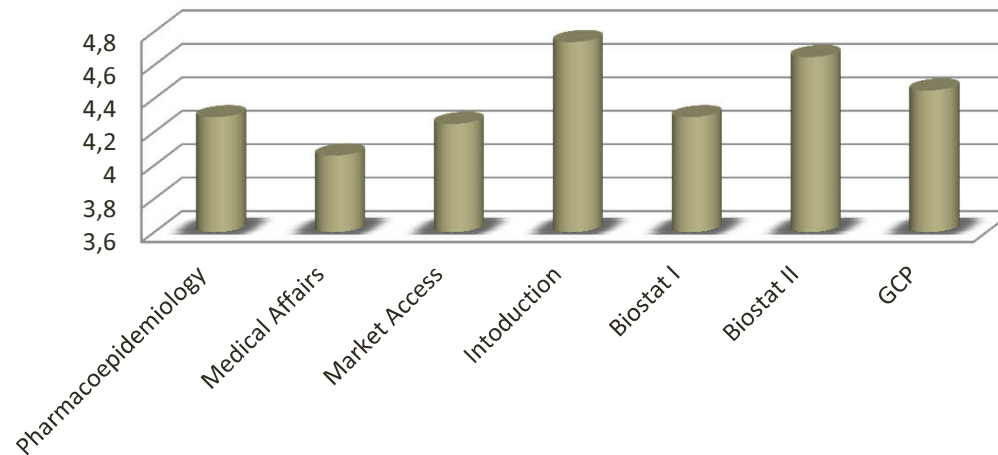
Students enrolled per course



# Spring 2013

- Excellent attendance (more than 90%)
- Requested MCQ return 100%
- Encouraging feedback on both content and facilities
  - 2014 plan considered the insights and ideas

**Average assessment per course**





## PROFESSIONAL STUDIES

PHARMACEUTICAL MEDICINE MODULES

Spring - Summer 2014

**ΣfEE**

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

Graduate School of Arts & Sciences  
 **DEREE**  
The American College of Greece

# Spring 2014

- **INTRODUCTION TO CLINICAL RESEARCH**

- 10 weeks course- March 20 to June 5 2014

The module will go through the main aspects of clinical research. By the end of the module the attendee should have learned what clinical research is, the rules and regulations under which it is executed, top level insight in 4 therapeutic areas and best practices in the field.

- **FROM GENETICS AND TRANSLATIONAL RESEARCH TO PHARMACOGENOMICS AND PERSONALIZED MEDICINE**

- 10 weeks course– starting March 20 to June 12 2014

This course will provide a comprehensive understanding of key genetic and pharmacologic principles in drug development and use.

The course is scientifically designed & executed in collaboration with the Biomedical Research Foundation of Academy of Athens



# INTRODUCTION TO CLINICAL RESEARCH

Welcome and course overview, why are clinical trials done, what are the key components of a study	K. Papageorgiou
Legal and regulatory framework, what was the evolution	V. Vazaiou
GCP principles	Eri Coroneou
From bench to bedside: How are drugs discovered, tested and approved	N. Baibas
Quality Assurance and quality by design, Risk management	Fotoula Dragatsi
Pharmacovigilance principles & requirements in clinical trials	Maria Polydorou
Neurology Trials	S. Papageorgiou
Respiratory Trials	Niki Georgetou
Endocrinology trials	Konstantinos Fenekos
Oncology Trials	George Papaxoinis
Pharmaco-economics	Kostas Athanasakis
Statistical Considerations	Christina Bamia
Clinical Operations	Fedra Mavroidi
	Fedra Mavroidi
CRA Communication Skills	Deree speaker
	Nora Sarikou
Workshop I: Clinical Operations	K. Bouza/K. Papageorgiou
	K. Bouza/K. Papageorgiou
Workshop II: Clinical Strategy	J Chondrellis / K Ntzamaras
	J Chondrellis / K Ntzamaras

# FROM GENETICS AND TRANSLATIONAL RESEARCH TO PHARMACOGENOMICS AND PERSONALIZED MEDICINE –BRFAA-IIBEAA

- **March 20** METHODS (DNA analysis, genome organization), applications in pharmacogenomics, computational genomics **DESPOINA SANOUDOU**
- **March 27** Basic concepts, Ethics, Personalized Medicine **KATIA KARALI**
- **April 3** : Pharmacodynamics and pharmacogenomics **ANDREAS PAPAPETROPOULOS**
- **April 10** : Pharmacogenomics of drug metabolism, transport and efflux. Pharmacogenomics in drug discovery and development **CONSTANTINOS TAMVAKOPOULOS**
- **May 8** : Infectious and inflammatory diseases (including respiratory) **GEORGINA XANTHOU**
- **May 15**: Cancer pharmacogenomics **EMA ANASTASIADOU**
- **May 22**: Cardiovascular disease **VANGELIS MANOLOPOULOS / DIMITRIS BEIS**
- **May 29**: Cancer/ Immunometabolism/ obesity **KARALIS**
- **June 5**: Nervous system, Behavioral, Addiction **ACHILLEAS GRAVANIS/ALEXIA POLLISIDIS**
- **June 12**: Role of pharmacogenomics in the adverse and toxic drug responses, toxicogenetics, drug receptors, regulatory proteins **ANDREAS PAPAPETROPOULOS**

# Spring 2014

- **GOOD CLINICAL PRACTICE COURSE FOR INVESTIGATORS**

- 2-day course 30-31 May 2014
  - By academics, regulators, pharma clinical research experienced staff
- To train new and experienced investigators

- **HEALTH OUTCOME RESEARCH AND MARKET ACCESS:**

- 2 day course 13-14 June 2014
  - In affiliation with University of Peloponese Health Policy Dept

An interactive two day session between medical pharmaceutical executives and academics. Presentations of academics will open up to discussions between medical pharmaceutical executives on the topics of market access.

- **PROJECT MANAGEMENT IN CLINICAL RESEARCH**

- 3 day course 13-14 June & 20 June 2014
  - Deree academics & Pharma experienced staff+ Workshop with Lab
- Project Management skills that are applicable to executing a clinical research project. A Phase IV workshop that will practically demonstrate all that was learnt will be included.

# GCP course for Investigators

- Historical aspects of GCP
- GCP Responsibilities
- Ethics review and CTA reviews
- Informed Consent
- IMP
- Inspections
- Workshops
- EMA inspector invited
- EOF inspector invited
- NEC members invited
- EOF Head of Clinical trials invited

# HEALTH OUTCOME RESEARCH AND MARKET ACCESS

Welcome & introduction	M.Geitona & B.Baroutsou
Improving health care value	M. Geitona / Health Economists
Registires and Real world data	Panel of Medical Director & Informatics
Health -Patient reported Outcomes studies	Panel of Health economists
Comparative effectiveness how is taken into account in reimbursement in Greece and Europe	Health Policy Experts
Wrap up od Day 1	M.Geitona & B.Baroutsou
Overview of Day 1 & Introduction to Day 2	M.Geitona &B. Baroutsou
Managing uncertainty in Market Access the way forward	Pharma executives
Sustainable health care budgets and pharmaceutical expenditure- Therapeutic protocols &EOPYY Registries	Panel of Health Policy experts &Economists
Reimbursement policy in Greece confusing or promising	Pharma executives in Market Access
How can EUNetHTA contribute to minimize EOPYY-payer uncertainty	Academic Health Economist
Close out	M.Geitona &B. Baroutsou

# PROJECT MANAGEMENT IN CLINICAL RESEARCH

Project Planning and Outline	DEREE
Project Management Tools	DEREE
Budgeting	DEREE
Resource Management	DEREE
Risk Management	DEREE
Quality Assurance	DEREE
Escalation process	DEREE
Negotiation Process	DEREE
Data Selection	DEREE
Data Management	DEREE
Vendor Management	DEREE
Change Management	DEREE
Conflict Resolution	DEREE
Leadership and Team Management	DEREE
Phase IV workshop: Applying Planning, , Resourcing, Budgeting	Pharma CR staff & DERE
	Lab
Phase IV workshop: Risk Management, QA Vendor Selection	Pharma CR staff & DERE
Phase IV Workshop: Vendor Management, Resource Management, Problem escalation and solving	Lab

# Spring 2014

- **QUALITY MANAGEMENT SYSTEMS OF PHARMACOVIGILANCE**

- 2 day course by PV-QA –QP Expert 9-10 May 2014

This module focuses on Quality Management Systems in Pharmacovigilance, including Management of Responsibility, Management of QMS Documentation, Management of Training and Personnel Records, Outsourcing Activities in Pharmacovigilance, Records Management and Quality Control Activities. The course will include case studies & workshops for practical application of knowledge acquired.

- **RETHINKING MEDICAL AFFAIRS' ROLE AS BUSINESS PARTNER AND LEADER - BUILDING NEW STRENGTHS**

- 2 day course by Deree academics and pharma MDs -executives 20-21 June 2014

A module for employed pharma Medical staff, Medical Directors, Medical Managers, Medical Advisors, Medical Science Liaisons, looking for input for the execution of their daily work. Lecturers will be academics and experienced pharma staff. Topics will cover Medical excellence, strategic vision, leadership skills and business acumen. The course will include case studies & workshops

# QUALITY MANAGEMENT SYSTEMS OF PHARMACOVIGILANCE

Introduction to Quality and QMS in Pharmacovigilance Efi Giannoula

Management Responsibility

Management of QMS Documentation

Management of Training and Personnel Records

Outsourcing Activities in Pharmacovigilance

Records Management

Measuring Pharmacovigilance Quality Management System Performance:Part I: Audits (Internal / External)

Measuring Pharmacovigilance Quality Management System Performance Part II: Inspections

Measuring Pharmacovigilance Quality Management System Performance Part III:

A. Key Performance Indicators

Measuring Pharmacovigilance Quality Management System Performance Part III:

B. Quality Management Review Meetings

Quality Control Activities in PhV

ISO 9001:2008 and Pharmacovigilance Regulation:

A. Basic principles of ISO 9001:2008 requirements

B. Performing the GAP Analysis

Unified GxP QMS Implementation:

A. The example of a multinational company

B. Challenges to face



# RETHINKING MEDICAL AFFAIRS' ROLE AS BUSINESS PARTNER AND LEADER - BUILDING NEW STRENGTHS

Course Introduction and scope	B.Baroutsou
Business leadership and acumen	DEREE academics
Breakout session	work in teams and report back case studies
Strategic Vision	Panel of Medical Directors
Breakout session	work in teams and report back case studies
Overview of Day 1 and Intro to Day 2	B.Baroutsou
Emotional intelligence and communication skills	DEREE academics
Breakout session	work in teams and report back case studies
Scientific and technological leadership	Panel Of Medical Directors- Panel of Medical Directors
Breakout session	work in teams and report back
Close out	BBaroutsou/ALL

# SFEE –DEREE CPE Ph Med core members 2014

- Graduate School of Fine Arts & Science
  - Dr A.Krepapa, Assistant Dean
  - V. Kyriakopoulou
- Scientific Advisors (volunteers)
  - Konstantina Papageorgiou
  - Efi Giannoula
  - Katia Karali
  - M.Geitona
  - B.Baroutsou
- SFEE Medical Directors Core team
  - T.Antachopoulou,N.Baibas,C.Kanavos
  - F.de Lorenzo,N.Papadimitriou,K.Papathoma
  - Barbara Baroutsou

Reviewed by SFEE Medical Directors Committee

Endorsed by SFEE Vice President Y. Vlontzos and SFEE Board of Directors

# Ag. Paraskevi Campus



# Autumn courses

- New for 2014 ( under design) based on SFEE Medical Directors Committee input
- Non interventional studies
- E medical strategies and tools
- Patient centricity

Note : Open to ideas & collaborations- Please feel free to contact us with your feedback

# OPEN DAY PRESENTATION AGENDA

## Pharmaceutical Medicine Modules

### March 4, 2014

- 15:00-15:15 Arrival
- 15:15-15:35 Welcome address - Thimios Zaharopoulos, Ph.D., ACG Provost
- 15:35-16:15 Welcome address – Presentation of Pharmaceutical Medicine Modules, Barbara Baroutsou, Chair of the Medical Director’s Committee of SFEE
- 16:15-17:00 Depiction of clinical research in GREECE. A recent study of the National School of Public Health (ESDY). Announcement of results. Dr K.Athanasakis

# Thank you for your attention

Q&As